

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

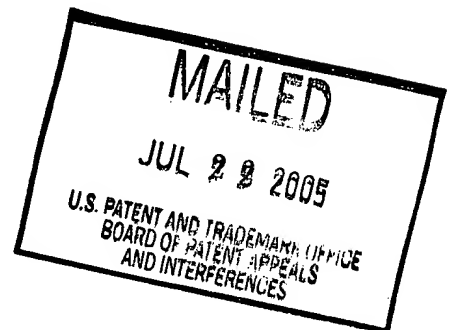
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte STEFAN BRACHT

Appeal No. 2005-0809
Application No. 09/937,534

ON BRIEF



Before SCHEINER, ADMAS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3, 6, 8 and 14-16. Claims 1 and 6 are representative of the subject matter on appeal, and read as follows:

1. Transdermal therapeutic system comprising a backing layer, at least one nicotine-containing layer or zone, and an additive comprising at least one monoterpene ketone, wherein the content of at least one monoterpene ketone in the nicotine-containing layer or zone is 0.1 to 5.0%--wt of the weight of the layer or zone.

6. Process for masking an unpleasant smell, caused by the presence of nicotine, comprising adding to a nicotine-containing layer or zone of a nicotine-containing transdermal therapeutic system, 0.1 to 5.0%--wt, based on the weight of the layer or zone, of at least one monoterpene ketone.

The examiner relies upon the following references:

Briskin et al. (Briskin)	3,559,655	Feb. 02, 1971
Defoney et al. (Defoney)	4,039,653	Aug. 02, 1977
Baker et al. (Baker)	5,362,496	Nov. 08, 1994
Majeti	5,559,554	Feb. 04, 1997
Yamaguchi et al. (Yamaguchi)	5,820,877	Oct. 13, 1998

Claims 1-3, 14 and 15 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Baker, Yamaguchi and Majeti. In addition, claims 6, 8 and 16 stand rejected under 35 U.S.C. § 103(a) as obvious over the above combination as further combined with DeFoney and Briskin. After careful review of the record and consideration of the issues before us, we reverse both rejections.

DISCUSSION

Claims 1-3, 14 and 15 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Baker, Yamaguchi and Majeti.

As set forth by the examiner, "[t]he claims are drawn to a transdermal therapeutic system (TTS) comprising a backing layer and an adhesive patch, where the patch comprises nicotine as a drug and a monoterpene ketone or essential oil containing a ketone." Examiner's Answer, page 3.

Baker is cited for teaching a transdermal delivery system comprising both a backing layer and an adhesive patch. See id. Baker is also cited for teaching transmucosal delivery systems that may include flavorants/taste masking compounds, such as peppermint and carvone. See id. The examiner asserts that such compounds are also well known for masking scent as well, and that

while the preferred presentation is a gum, lozenge or tablet, the use of ointments and gels is also disclosed. See id. The rejection asserts that “[t]he transdermal formulation includes nicotine as a drug and essential oils. The essential oils suggested are spearmint and peppermint oil, along with monoterpene ketones and alcohols such as 1-menthol and carvone (col. 6, lin. 6-59; col. 20, lin. 26-36.)” Id. at 3-4. The rejection acknowledges that “[t]hough the reference discloses transmucosal delivery of nicotine and carvone, it does not disclose the formulation in a patch presentation.” Id. at 4.

Yamaguchi is cited for teaching a percutaneous or permucosal patch drug preparation comprising a backing layer, an adhesive layer and nicotine as a drug. See id. The reference is also relied upon for teaching that monoterpene alcohols, such as menthol and mentha oil, may be used as adsorption enhancers, but the rejection again acknowledges that the reference “is however silent to the inclusion of monoterpene ketones.” Id. The examiner asserts, however, that the Yamaguchi patent discloses that oral mucosal patches comprising nicotine and essential oils are known in the art, and that “[a] skilled artisan would follow this motivation as evidenced by [Yamaguchi] to combine the transmucosal formulation of [Baker] into the patch device of [Yamaguchi].” Id.

Majeti is relied upon for teaching a transdermal or transmucosal delivery system, wherein the delivery system comprises a backing layer, nicotine and menthol as an additive. According to the examiner,

The reference establishes the art recognized nexus between transdermal and transmucosal formulations. A skilled artisan would have followed this motivation to expect a reasonable level of success of a transmucosal nicotine patch by combining the nicotine/carvone formulation of [Baker] into the transmucosal patches of [Yamaguchi], since [Majeti] discloses many of the same

support excipients (cellulose polymers) (col. 4, lin. 59-col. 5, lin. 31). Sharing carrier excipients such as disintegrants, polymers and binders, shows the compatability of two formulations. . . .

* * *

With this in mind a skilled artisan would have been motivated to combine the teachings of the art and modify them to provide an optimal presentation. [Baker] provides a transmucosal formulation comprising nicotine, flavor/taste making agents such as menthol or carvone, and where both monoterpene alcohols and ketones were suggested (menthol, and carvone), and could be used interchangeably. A skilled artisan would have followed the suggestion of [Yamaguchi] to include menthol and other monoterpene alcohols into transdermal formulations. Though known in the art, [Majeti] would have provided the teaching that, formulations for both transdermal and transmucosal delivery are interchangeable and can be prepared similarly. . . . This would have been motivation enough for a skilled artisan to include either carvone or menthol into a transdermal preparation comprising nicotine in order to provide better adsorption. . . .

Id. at 4-6.

Appellant argues that the rejection misrepresents the teachings of Baker. See Appeal Brief, page 4. In Baker, while transdermal delivery is accomplished by means of a patch, the transmucosal delivery system is preferably in the form of a lozenge. Appellants contend that there is no disclosure of a patch containing a monoterpene ketone, and there is nothing in Yamaguchi or Majeti that would teach or suggest its inclusion in a patch. See id. at 5-6. We agree.

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (citations omitted). The test of obviousness is “whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention.” In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

The examiner relies on Baker for teaching the use of a transmucosal nicotine delivery system containing a monoterpene ketone, i.e., carvone. Baker teaches the preferred delivery system is a lozenge, but also teaches other oral dosage forms such as capsule, gum, tablet, suppository, ointment, gel, pessary, membrane and powder. See Baker, Col. 16, lines 9-16. In the context of the nicotine lozenge, Baker teaches that the lozenge may contain a flavorant, including essential oils “such as peppermint, spearmint and the like; or other flavor such as aniseed, eucalyptus, 1-menthol, carvone, anethole and the like, to mask the taste of nicotine.” See id. at Col. 20, lines 26-32.

The examiner relies on Yamaguchi and Majeti to provide the motivation to incorporate the monoterpene ketone, carvone, into a patch delivery system. Yamaguchi is relied upon for teaching the use of menthe oil and menthol, monoterpene alcohols, as adsorption enhancers in nicotine patch delivery system. Majeti is relied upon for teaching a nicotine patch that may be used for either transdermal or transmucosal delivery, which the rejection over generalizes as providing a teaching of the equivalence of transmucosal and transdermal delivery systems.

The rejection also errs in stating that the references suggest that monoterpene alcohols and monoterpene ketones may be used interchangeably because Baker teaches that both may be used as flavorants. While Yamaguchi teaches that the monoterpene alcohols may be used as adsorption enhancers, there is no teaching or suggestion provided by any of the references that carvone may also be used as an adsorption enhancer enhancer. Moreover, there is no teaching or suggestion relied upon by the rejection that either Yamaguchi or Majeti teaches or suggests the use of a flavorant in a patch

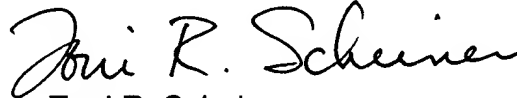
system, which is carvone's only disclosed use. We therefore find that the rejection does not set forth a prima facie case, and it is reversed.

Claims 6, 8 and 16 stand rejected under 35 U.S.C. § 103(a) as obvious over the combination of Baker, Yamaguchi, Majeti, Briskin and DeFoney. As Baker, Yamaguchi and Majeti are relied upon as above, and as Briskin and DeFoney do not remedy the deficiencies of the combination, this rejection is also reversed.

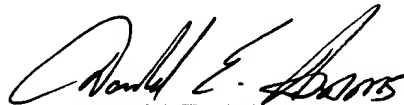
CONCLUSION

Because the examiner did not set forth a prima facie case of obviousness, we are compelled, based on the record before us, to reverse both rejections under 35 U.S.C. § 103(a).

REVERSED



Toni R. Scheiner
Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

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